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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,467	08/20/2003	George V. Guittard	AR02366USACON3	8204

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EXAMINER	
GEORGE, KONATA M	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,467	GUITTARD ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-37 and 41-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-37 and 41-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/14/06; 1/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 35-37 and 41-43 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on April 14, 2006 and September 12, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Action Summary

2. The rejection of claims 35-37 and 41-43 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 15 of US Patent 6,262,115 is hereby withdrawn as a terminal disclaimer was filed.

3. The rejection of claims 35-37 and 41-43 under 35 U.S.C. 102(a) as being anticipated by Rantala is being maintained for the reasons stated in the previous office.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 35-37 and 41-43 are rejected under 35 U.S.C. 102(a) as being anticipated by Rantala (WO 96/12477).

Rantala discloses in Figures 1 and 2 a "substantially" constant plasma concentration of oxybutynin for 24 hours from peroral dose one 10 mg controlled release tablet. The relatively constant plasma concentration for 24 hours is evidence that oxybutynin must have been released at a substantially zero order rate of release over a 24 hour period. See also claims 16-17. Tables 2 and 4 on pages 8 and 9 teach that the oxybutynin is administered with a hydrochloride salt. Since the treated condition includes neurogenic bladder (e.g. urine leakage or incontinence), applicant's "management of incontinence" is met. It is also taught on page 5, lines 25-26 that the composition is in the form of tablets. The prior art teaches the plasma oxybutynin/desethylmetabolite ratio from 0.2 ng/ml to 30 ng/ml for the oxybutynin and 2.5 ng/ml to 150 ng/ml for the desethylmetabolite which falls within the claimed ratio.

Response to Arguments

5. Applicant's arguments filed February 8, 2006 have been fully considered but they are not persuasive.

Applicants argue that the claimed oxybutynin/desethyl metabolite ratio of the instant invention is not taught in the prior art. The examiner disagrees. The invention as claimed is directed towards treating involuntary incontinence by administering orally a dosage form comprising 5 mg to 250 mg of a member selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt. It is the position of

the examiner that the oxybutynin/desethyl metabolite ratio in the plasma as claimed by applicant is a characteristic of the composition. The prior art teaches administering a 10 mg controlled release formulation of oxybutynin or its pharmaceutically acceptable salt. It is the position of the examiner that since the drug dosage range is within the claimed range and the drug is the same then the oxybutynin/desethyl metabolite ratio would also be within the claimed range. Applicant does not teach any other characteristics of the drug form that would produce the claimed ratio. Therefore, any drug form containing oxybutynin or its salts in the claimed range would meet the ratio limitation. Applicant would need to show why the drug dosage form of the prior art would not meet the oxybutynin/desethyl metabolite ratio as claimed.

Conclusion

6. Claims 35-37 and 41-43 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER